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AkzoNobel

Tomorrow's Answers Today

MR#351022

January 8, 2013

US EPA Office of Pollution Prevention and Toxics
EPA East Building Room 6428
Attn: Section 8(e)
1201 Constitution Avenue, NW
Washington, DC 20004



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Cc: Polymer Chemicals bv
Arkema France
Pergan GmbH
United Initiators GmbH & Co. KG

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SUBJECT: TSCA 8(e) Notice



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Dear TSCA Section 8(e) Coordinator:

On behalf of Akzo Nobel Polymer Chemicals LLC we are submitting terminal results on an OECD 422 Combined Repeat Dose Toxicity with Reproduction/Developmental Toxicity Screening Test, with tert-butyl peroxy-pivalate CAS# 927-07-1.

Four groups of Hsd.Brl.Han:Wist rats (n=12/sex/group) were administered orally (by gavage) once a day at 0 (vehicle only), 50, 150 and 310 mg/kg bw/day. All animals of the parent (P) generation received test item or vehicle prior to mating (14 days) and throughout mating. Test item or vehicle was administered to male animals post mating up to the day before the necropsy. For females with living pups, test item was administered through the gestation period and up to lactation days 3 — 6, i.e. up to the day before the necropsy.

Clinical Observations

Test item related salivation appeared in male and female animals administered with 310 and 150 mg/kg bw/day groups with a dose related onset and incidence.

Body Weight

A test item related depression of the body weight gain was detected at 310 mg/kg bw/day with respect to controls in male animals during the entire study and in female animals during lactation period.

Food Consumption

A test item influence on the mean daily food consumption was observed in male and female animals at 310 and 150 mg/kg bw/day. The mean daily food consumption was less than in the control group at 310 and 150 mg/kg bw/day doses during the first week of treatment (male), during the premating (female) and at 310 mg/kg bw/day between lactation days 0 and 4.

Hematology

Statistically significant differences between the control and dosed groups in some hematological parameters were of low magnitude and values remained well within the historical control ranges (less white blood cell count (WBC) in male animals administered with 310 or 50 mg/kg bw/day; lower percentage of neutrophil granulocytes (NEU) at 310 mg/kg bw/day and

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monocytes (MONO) at 50 mg/kg bw/day and a higher percentage of lymphocytes (LYM) at 310 mg/kg bw/day in the female animals, with respect to controls).

Clinical Chemistry

The mean concentration of total bilirubin (TBIL) was slightly less and the mean calcium (Ca^{2+}) levels were higher than in the control group in the male animals dosed with 310 mg/kg bw/day. In the female animals, the mean creatinine (CREA) and glucose (GLUC) concentrations were slightly below the value of control.

Organ Weights

Statistically significant higher mean weights of kidneys (absolute and relative to body and brain weights) were noted in male animals at 310 mg/kg bw/day dose. Minor changes were also noted for the kidney weights (absolute and relative to body and brain weights) in male animals at 150 and 50 mg/kg bw/day.

In female animals, similar findings were observed at 150 mg/kg bw/day, but not in the 310 mg/kg bw/day. The kidney weight relative to body weight exceeded the control value in females at 310 mg/kg bw/day; however the fasted body weight of this group was significantly less than in the control.

Statistical significances were noted in female animals for the higher mean absolute liver weight at 150 mg/kg bw/day and for liver weights relative to body and brain weight at 310, 150 and 50 mg/kg bw/day doses, and for mean liver weight relative to body weight in male animals at 310 mg/kg bw/day. The liver weight changes were within the historical control ranges and there were no related pathological findings at the clinical chemistry and histopathology investigations. Statistical differences in the spleen weights in male animals at 310 mg/kg bw/day (relative to body weight) and at 150 mg/kg bw/day (absolute and relative to body and brain weight) were well within the historical control range.

F1 (Offspring) Generation

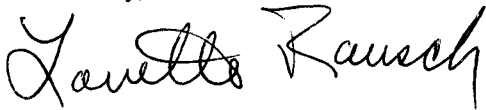
The extra uterine mortality of pups was significantly higher in 310 mg/kg bw/day group than in the control group between postnatal days 0 and 4. 40 % of live born pups were missing or found dead. The litter mean of viable pups was also less at 310 mg/kg bw/day with respect to control.

Cold, not suckled (no milk in the stomach) pups and cachexia were observed with high incidence in litters at 310 mg/kg bw/day. The number and litter means of these signs were significantly higher than in the control group. In two pups, cyanotic skin was observed.

The mean litter weight was significantly less than in the control group at 310 mg/kg bw/day on postnatal day 4, and the litter weight gain was also less than in the control between days 0 and 4. The mean pup weight on day 4 and the mean weight gain of pups between days 0 and 4 was significantly reduced for some litters (3/6) at 310 mg/kg bw/day.

Please contact me at (312) 544-7061 if you have any questions regarding this letter.

Sincerely,



Louette Rausch

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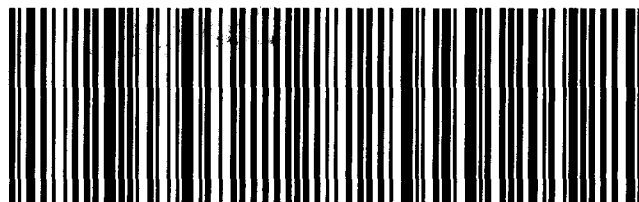
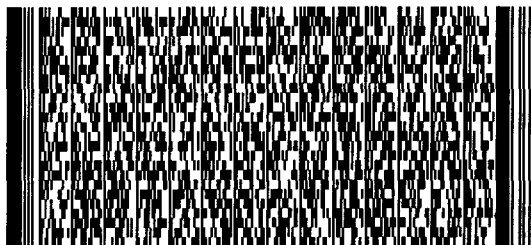
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